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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,268	06/23/2003	Deryck J. Williams	12557-011001	9137

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FISH & RICHARDSON PC  
P.O. BOX 1022  
MINNEAPOLIS, MN 55440-1022

EXAMINER
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HUTSON, RICHARD G

ART UNIT	PAPER NUMBER
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1652

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/22/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

# Office Action Summary

Application No.

10/602,268

Applicant(s)

WILLIAMS ET AL.

Examiner

Richard G. Hutson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 26 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 9-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 12 is/are allowed.
- 6) ☒ Claim(s) 9-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicant's amendment of claims 9-11 and the cancellation of claims 1-8 and 13-83, in the paper of 10/26/2006, are acknowledged. Claims 9-12 are still at issue and are present for examination. Applicants' arguments filed on 10/26/2006, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polypeptide having the complete amino acid sequence of SEQ ID NO: 9, wherein said polypeptide has phosphoethanolamine n-methyltransferase activity, does not reasonably provide enablement for any polypeptide having a mere 80% identity to the amino acid sequence of SEQ ID NO: 9. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

This rejection was originally stated in the previous office action as it applied to previous claims 9-11. In response to the rejection applicants have amended the claims and traverse the rejection as it applies to the newly amended claims.

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Applicants first note that applicants have amended their claims 9-11 to require that the claimed polypeptide has methyltransferase activity.

Second as described in the context of arguing the previous written description rejection applicants submit that the present specification presents considerable guidance for one skilled in the art wishing to make functional proteins having 80% identity to SEQ ID NO: 9. Applicants submit for example that Table 3 of the specification identifies 4 motifs in SEQ ID NO: 9 that are believed to be important for methyltransferase activity. Additionally applicants submit that Figure 7 of the specification provides an alignment of the sequences of *A. sum*, *H. contortus*, *M. incognita*, *S. stercoralis* and *C. elegans* PEAMT-1-like enzymes and polypeptides and this alignment allows one to readily identify conserved regions among the disclosed PEAMT1-like enzymes. Applicants submit that taken together, the identification of motifs and the alignment provide considerable guidance for one making functional proteins having at least 80% identity to SEQ ID NO: 9.

Applicant's complete argument is acknowledged and has been carefully considered, however, is found non-persuasive for the reasons previously made of record and repeated herein.

Applicant's amendment of the claims requiring that the claimed polypeptides have methyltransferase activity is acknowledged and helpful in moving prosecution forward, however, the claims remain rejected because it continues to be the case that applicants have not enabled the vast scope of those polypeptides included within the claimed genus.

Applicants discussion regarding applicants disclosure of three PEAMT1-like enzymes from parasitic nematodes in addition to SEQ ID NO:9 as well as the two splice variants of *C. elegans* encoding a PEAM1-like enzyme are acknowledged, however, such is not considered to be sufficient guidance to enable the breadth of the claimed genus drawn to those molecules having a mere 80% identity to the amino acid sequence of SEQ ID NO: 9. In addition to the variability that exists within the structural genus of those polypeptides having a 80% identity to SEQ ID NO:9, additional variability exists within the functional genus as to those polypeptides having methyltransferase activity. That is the variability that lies in the substrates and products associated with the methyltransferase of the reported PEAMT1-like enzymes.

Further it is recognized that applicants submit that they have identified a number of motifs that exist between the reported PEAMT1-like enzymes, however, the relevance of these motifs with respect to a specific activity remains in question.

Thus while applicants have provided some guidance as to the relationship between the disclosed molecules, it continues that applicants have not provided sufficient guidance to enable the large number of molecules and the associated variability of the molecules having any methyltransferase activity.

It remains that applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any polypeptide comprising a mere 80% identity to the amino acid sequence of SEQ ID NO: 9, wherein said polypeptide has any methyltransferase activity. The scope of the claims must bear a

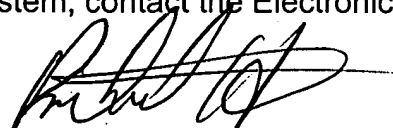
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reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of those polypeptides having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G. Hutson whose telephone number is 571-272-0930. The examiner can normally be reached on M-F, 7:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Richard G Hutson, Ph.D.  
Primary Examiner  
Art Unit 1652

rg  
1/9/2007